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09/982,307	10/16/2001	Ganapati R. Mauze	10003714	7843

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AGILENT TECHNOLOGIES, INC.  
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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/982,307

## Applicant(s)

MAUZE ET AL.

## Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-13 and 21-43 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 10, 2004 has been entered.

### ***Information Disclosure Statement***

2. The references were clearly submitted, since a CD is in the application.

### ***Claim Interpretation***

3. Prior to examination, the claims must be analyzed, since claim construction precedes application of the statutory requirements for patentability.

Applicant has extensively amended claim 21, but nearly all of the amendment fails to impose any structure on the apparatus. In claim 21, as noted previously, the term "cartridge" carries no weight whatsoever, and anything may be a "cartridge". The language such as "configured to be inserted" or "designed to perform" or "shaped to define" all represent functional limitations in an apparatus. As MPEP 2114 makes clear, "claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." No specific structure is required or imposed by the term "configured to be inserted into an instrument" other than that a sensor device of some sort can analyze the cartridge in some way.

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The new phrases such as “mechanically securable to an associated sensing cartridge” impose no structural requirements on the cartridge since any structure whatsoever is “mechanically securable”. Similarly, “physically mates” simply means that the elements are adjacent to one another. The phrase “slot shaped” is entirely functional since any shape whatsoever is slot shaped. This can be exemplified by a children’s wooden puzzle, where wooden trucks or airplanes or animals are fitted into slots.

As noted previously, the first paragraph of claim 21, with the “configured” and “designed” and “shaped” language, simply requires a component. There is no particular structural elements required by this paragraph whatsoever. The second paragraph requires that the “base element” component have a fluid entry port, the third paragraph requires a “fluid reservoir” and the fourth paragraph requires an “operator”.

However, where claims 34-43 require “fluid communication” between the sensor cartridge and the companion cartridge, this is a structural element which is met by the currently cited prior art.

The claims do include two new requirements that impose some amount of structure. First, the limitation of “substantially planar” implies that the device is somewhat planar. However, all of the figures, exemplified in figure 7 of Lipshutz, disclose devices that are clearly “substantially planar”. Second, the limitation that the “sensing cartridge” is distinct from the “companion cartridge” imposes some structure, but the cited Lipshutz reference teaches an external reader, which is an external “sensing cartridge” as noted in the rejection.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 21-23, 26-34, 36, and 38-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al (U.S. Patent 5,856,174).

Lipshutz teaches a “cartridge” (see figure 3 and column 2, lines 15-43) and an analytical instrument (see figure 3) of claim 21 which comprises

A base element that can be inserted into an analysis device (see column 11, lines 48-52), where Lipshutz expressly teaches that the reaction chamber portion can be “mated with a reusable base unit (see column 26, lines 43-67)” which provides some elements.

Lipshutz further teaches the presence of an entry port (see column 16, lines 15-18, where an inlet port for the entire device is suggested),

A fluid reservoir (see column 26, lines 43-67 and see column 16, lines 18-20, where a “storage chamber” is discussed),

And where these are in fluid communication using a fluid transport system (column 2, line 23),

Where the cartridge performs an operation including a hybridization reaction chamber (see column 2, lines 26-28), or an amplification chamber used for PCR amplification (see column 2, lines 48-53 and column 6, lines 28-67).

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As noted previously, Lipshutz teaches that the "cartridge" may be connected to a sensing "cartridge" either directly or indirectly (see column 11, lines 48-52) and is thereby shaped to interact with the remainder of a "diagnostic instrument".

With regard to claim 22, Lipshutz teaches the use of a fluid interface such as capillary electrophoresis for detection (see column 12) as well as by a mechanical/electrical interface into a reader device (column 13, lines 25-35).

With regard to claims 23, Lipshutz teaches a reagent storage system in the cartridge (see column 16, lines 18-20).

With regard to claims 26-28, 36, 40, 42, 43, Lipshutz teaches thermocycling to perform PCR (see column 6, lines 28-67).

With regard to claims 29, 32, 33, Lipshutz teaches fluid transport systems (see column 2, line 23, for example) (Claims 32 and 33 do not structurally delimit the device since no structural element is included which effects the process step of mixing).

With regard to claim 30, Lipshutz teaches fluid systems which transport fluid to some chambers thereby increasing their volume (see column 2, lines 15-43).

With regard to claim 31, 38, 39, Lipshutz teaches a waste retrieval system (see figures 4A-C, where element 414 is the waste reservoir).

With regard to claim 34, Lipshutz teaches a device in which a sensor device and a companion cartridge are integrated on a single device in fluid communication with one another (see figure 3, for example).

With regard to claim 41, Lipshutz teaches lysis of cells for preparation of DNA (see column 5, lines 50-67).

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***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 24, 25, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al (U.S. Patent 5,856,174) in view of Leiner et al (U.S. Patent 6,037,178).

Lipshutz teaches the limitations of claims 21-23, 26-34, 36, and 38-43 as discussed above. Lipshutz does not teach the use of calibration cartridges.

Leiner teaches the use of calibration cartridges (see abstract and column 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use a calibration cartridge as taught by Leiner with the device of Lipshutz since Liener states "It is an object of the present invention to propose

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methods of quality control and quality control liquids which will permit first a control measurement and then measurement of a specimen by means of one and the same single-use cartridge, in addition to providing information on the reliability of the analyzer, or rather, reliability and accuracy of the individual sensors contained in the single-use cartridge (see column 3, lines 45-51).” So an ordinary practitioner would have been motivated to include a calibration cartridge in order to improve the reliability and accuracy of the device.

### ***Response to Arguments***

9. Applicant's arguments filed November 9, 2004 have been fully considered but they are not persuasive.

Applicant argues that Lipshutz does not teach a “sensing cartridge” or “diagnostic instrument”. That argument is not addressed to the claim, which never requires the presence of either of these elements. The claims are drawn solely to a “companion cartridge”. There are no requirements in the claim, as noted in the claim interpretation paragraph above, which impose any requirement that a “sensing cartridge” or “diagnostic instrument” be present. (Though, in fact, Lipshutz has an “external reader” which would probably meet a generic “diagnostic instrument” or “sensing cartridge” limitation). Applicant's entire argument attempts to read these elements into a claim which does not recite them.

The 103 rejection is maintained since the arguments are solely directed towards the 102 rejection over Lipshutz.



***New Ground of Rejection – Necessitated by Amendment***

***Claim Rejections - 35 USC § 112***

10. Claims 21-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

MPEP 2163.06 notes " If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen , 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

Here, the amendment to claim 21 incorporates new matter. The amendment does not point out any basis for the new phrase "mechanically securable" or for the phrase "physically mates". A careful review by the examiner of the specification failed to identify any support for these new limitations. Unlike the new limitation "planar" for example, which while also lacking literal support can at least be seen as present in the figures, the limitations rejected above appear to have no basis in either the figures or in the specification. Since no basis has been found to support the new claim limitation in the specification, the claim is rejected as incorporating new matter.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

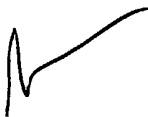
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jeffrey Fredman  
Primary Examiner  
Art Unit 1637

12/3/04